Clinical Policy Title: Genetic testing for breast and ovarian cancer

Clinical Policy Number: 02.01.02

Effective Date:	**September 1, 2013**
Initial Review Date:	March 21, 2013
Most Recent Review Date:	May 19, 2017
Next Review Date:	May 2018

Policy contains:

- BRCA1/BRCA2 testing for breast and ovarian cancer.
- BART™ (BRCAnalysis® Rearrangement Testing).

Related policies:

CP# 02.01.14 Gene expression profile testing for breast cancer

ABOUT THIS POLICY: *AmeriHealth Caritas has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas' clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by AmeriHealth Caritas when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. AmeriHealth Caritas' clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. AmeriHealth Caritas' clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas will update its clinical policies as necessary. AmeriHealth Caritas' clinical policies are not guarantees of payment.*

Coverage policy

AmeriHealth Caritas considers the use of BRCA 1, BRCA 2, and BART™ to be clinically proven and, therefore, medically necessary for women or men at high risk for BRCA gene mutation, when the following criteria are met:

✓	**Patient criteria:** **Either A, B, C, *or* D must be met**
	A. Individual's genetic predisposition: 1. If of ethnic descent associated with deleterious mutations (e.g., founder populations of Ashkenazi Jewish), then no additional family history is required. 2. A first- or second-degree relative with a known BRCA 1 or BRCA 2 gene mutation. 3. Women with multiple first- and/or second-degree blood relatives with breast cancer.
	B. Personal history of breast cancer plus one or more of the following: 1. Diagnosed age ≤ 45 years, with or without family history.

✓	**Patient criteria:** **Either A, B, C, *or* D must be met**
	2. Diagnosed age ≤ 50 years or two breast primaries, with ≥ one close blood relative with breast cancer ≤ 50 years, or ≥ one close blood relative with ovarian cancer. 3. Diagnosed at any age, with ≥ two close blood relatives with ovarian cancer at any age. 4. Diagnosed at any age, with ≥ two close blood relatives with breast cancer, especially if ≥ one woman is diagnosed before age 50 or has two breast primaries. 5. Close male blood relative with breast cancer. 6. Personal history of ovarian cancer.
	C. Personal history of ovarian cancer plus one or more of the following: 1. ≥ One close blood relative with ovarian cancer. 2. ≥ One close female blood relative with breast cancer at age ≤50 or two breast primary cancers. 3. ≥ Two close blood relatives with breast cancer. 4. ≥ One close male blood relative with breast cancer.
	D. Personal history of male breast cancer if one or more of the following is present: 1. ≥ One close male blood relative with breast cancer. 2. ≥ One close female blood relative with breast or ovarian cancer. 3. A first- or second-degree relative with a known BRCA1 or BRCA2 gene mutation.

BART testing may be offered to individuals who otherwise meet the criteria for BRCA1 or BRCA2 testing but are found to be negative on BRCA1 or BRCA2 testing.

Individuals considered for testing should be offered genetic counseling by an appropriately trained genetic counselor prior to testing with BRCA1, BRCA2, or BART. Further diagnostic studies may be covered including annual mammography and magnetic resonance imaging (MRI) of the breast. Prophylactic bilateral mastectomy and salpingo-oophorectomy are covered for individuals who have a positive test.

For purposes of genetic linkages, “close family relative” is defined as mother, sister, daughter, grandmother, granddaughter, aunt, father, brother, son, grandfather, grandson, or uncle.

In Pennsylvania, individuals not meeting any of the above criteria may be offered BRCA1, BRCA2, or BART testing if determined through both independent formal genetic counseling and a validated quantitative risk assessment tool to have at least a 10 percent pre-test probability of carrying a BRCA1 or BRCA2 mutation.

AmeriHealth Caritas may require some form of genetic counseling for each test, but it does not have to be by a geneticist or genetic counselor, who may not be readily accessible to consumers in certain areas of Pennsylvania.

A genetic test is considered medically necessary if the results are expected to make a difference in the

recipient's care or his or her treatment plan, or the recipient (or a responsible family member or legal guardian) intends to use the information in making decisions about his or her care or treatment plan. An example would be family planning decisions or planning of other indicated testing in light of the diagnosis. Genetic testing is medically necessary if it is a currently accepted method of diagnosis of a condition or disease.

In the event that the member has no knowledge of family history because of adoption or other limitations on obtaining family history, Pennsylvania benefits allow BRCA1 or BRCA2 testing if the testing is considered medically necessary and the results will influence care management.

All requests may be reviewed individually, even if the above guideline criteria are not met.

Limitations:

All other uses of BRCA1, BRCA2, and BART are not medically necessary, including genetic risk assessment of breast and/or ovarian cancer.

Other limitations:

- In some states, coverage of BRCA1/BRCA2 testing is limited to members < 67 years of age.
- For testing panels, including, but not limited to, multiple genes or multiple conditions, and in cases where a tiered approach or method is clinically available, testing would be covered only for the number of genes or tests that are reasonable and necessary to obtain necessary information for therapeutic decision making.
- Individual has not previously received genetic testing for the disease or condition. In general, diagnostic genetic testing for a disease should be performed once in a lifetime.

Alternative covered services:

Standard diagnostic studies such as physical examination, mammography, ultrasound, and surgical biopsy.

Background

Breast cancer occurrence is similar for Caucasian and African American women, with an incidence of 120 new diagnoses per 100,000 women per year, although Asian and Hispanic women have a lower incidence of 100 new diagnoses per 100,000 women per year (CDC, 2011). Mortality rates have declined over the past decade; however, there are significant disparities in mortality rates. The Centers for Disease Control and Prevention (CDC) report that African American women have the highest rate, at 32 deaths per 100,000 women per year, whereas the rates for Caucasian women, Hispanic women, and Asian women are at 25 deaths, 15 deaths, and 13 deaths per 100,000 women per year, respectively (CDC, 2011). Because of the high incidence of breast cancer, the second-leading cause of cancer death in women, new ways to improve diagnosis have been sought.

In 5 percent to 10 percent of women with breast cancer, a significant family history can be found. For those with a strong family history of breast or ovarian cancer, mutations of the BRCA1 or BRCA2 genes account for the majority of cases. The American Congress of Obstetricians and Gynecologists (ACOG) estimates between one in 300 and one in 800 individuals within the general population carry a mutation in the BRCA1 or BRCA2 gene (ACOG, 2009). The BRCA1 and BRCA2 genes in their unmutated states act as suppressors of breast or ovarian cancer. The mutation removes this protective attribute, enhancing the risk of such malignancies. Mutation of BRCA1 or BRCA2 does not guarantee that the individual will develop breast or ovarian cancer but that the individual will have a higher risk of developing breast or ovarian cancer. A meta-analysis estimated the risk by age 70 years of developing breast cancer and ovarian cancer in women who are BRCA1 or BRCA2 positive to be 57 percent and 40 percent, respectively (Chen, 2006).

There are three main types of tests used to detect BRCA1 and BRCA2 gene mutations:

- Full nucleotide screening — This comprehensive, full sequencing analytic tool is considered the gold standard, as it can detect single-point mutations in either the BRCA1 or BRCA2 gene.
- Allele-specific oligonucleotide hybridization (ASO) — ASO analysis is generally used if there is an already-known BRCA mutation within the family. This test detects the carrier potential of the individual being tested. If positive, more full nucleotide screening would be considered.
- Protein truncation assays — Protein truncation assays detect shortened protein products. However, it will not detect proteins of normal length that may have aberrant sequences.

BRCAnalysis Rearrangement Testing (BART) is a genetic test used to detect large genomic rearrangements in BRCA1 and BRCA2 not detected through BRCA1/BRCA2 testing. The BRCA1 and BRCA2 mutations do not represent all errors of the tumor suppression gene. Other large rearrangements of the BRCA genes have been associated with higher risk of breast and ovarian cancers. Studies by Palma (2008), Walsh (2006), and Unger (2000) have found evidence of large rearrangements of the BRCA genes associated with higher risk of breast and ovarian cancers. To date, studies have not demonstrated reductions in mortality associated with detection of large rearrangements by using BART. However, because of increased detection of breast and ovarian cancer risk in BRCA1/BRCA2-negative patients who otherwise share the same breast and ovarian cancer risk, current recommendations are to test such individuals with BART.

Other genetic tests do not have population-based studies or peer-reviewed papers to demonstrate their impact and are considered investigational and not medically necessary. These include testing for single nucleotide polymorphisms (SNPs), RAD51C, CHEK2, CASP8, TGFB1, Ataxia Telangiectasia, and BRIP1 PALB2. Because of concerns with interpretation of test results, it is currently recommended that ordering and interpretation of results be performed in conjunction with a trained geneticist.

Individuals found to have the BRCA1 or BRCA2 germline mutation should be offered genetic counseling. The National Cancer Care Network (NCCN) guidelines indicate screening for breast cancer should begin 10 years prior to the age of diagnosis of the youngest family member. Men or women may consider annual mammography combined with MRI studies of the breasts with aggressive intervention if those studies detect disease. Lee (2008) found this strategy improved life expectancy by one year but did result in a rate between 11 percent and 30 percent higher of biopsies for benign disease.

Prophylactic mastectomy and salpingo-oophorectomy may be options for those at very high risk of disease. Among high-risk women and mutation carriers, risk-reducing mastectomy decreased breast cancer by 85 percent to 100 percent and breast cancer mortality by 81 percent to 100 percent compared with women without surgery; risk-reducing salpingo-oophorectomy decreased breast cancer incidence by 37 percent to 100 percent, ovarian cancer by 69 percent to 100 percent, and all-cause mortality by 55 percent to 100 percent (Moyer, 2014).

Searches

AmeriHealth Caritas searched PubMed and the databases of:

- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality's National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services (CMS).

We conducted searches on April 15, 2017. Search terms were: "prophylactic mastectomy," "salpingo oophorectomy," "breast neoplasms" [MeSH], "ovarian neoplasms" [MeSH] and "BRCA."

We included:

- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- **Guidelines based on systematic reviews.**
- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

Policy updates:

May 2014

AmeriHealth Caritas identified no new systematic reviews, economic analyses, or evidence-based guidelines for this policy update.

May 2015

AmeriHealth Caritas identified no new systematic reviews, economic analyses, or evidence-based guidelines for this policy update.

April 19, 2016

Added the summary of clinical evidence section. Updated Local Coverage Determinations (LCDs).

April 5, 2017

Writing in *UpToDate*, Burst (2017) assessed the ability of contemporary genetic testing procedures to influence management of cancer of the breast:

> "To guide clinical decision-making, gene expression profiles such as the RS, EndoPredict, the Breast Cancer Index (BCI), and the PAM50 intrinsic subtype assay have been developed to identify patients with such a low chance of recurrence that the absolute benefit of chemotherapy may not justify the risk of toxicities. By contrast, patients with higher scores on these assays have a sufficiently high risk of recurrence despite endocrine therapy that the addition of chemotherapy outweighs the risk of toxicities. Moreover, given that the response to treatment is not uniform among all cancers, these assays may identify those cancers that, based on their biologic profile, are likely to have an excellent outcome with endocrine therapy alone versus those in which the addition of chemotherapy would substantially reduce the risk of recurrence."

Summary of clinical evidence:

Citation	Content, Methods, Recommendations
Nelson, et al. (2005) Genetic Risk Assessment and BRCA Mutation Testing for Breast and Ovarian Cancer Susceptibility: Evidence Synthesis	**Key points:** • To determine the balance of benefits and adverse effects of screening based on available evidence. The target population includes adult women without preexisting breast or ovarian cancer presenting for routine care in the United States. • Relevant papers were identified from multiple searches of MEDLINE® (1966 to October 1, 2004); Cochrane Library databases; and reference lists of pertinent studies, reviews, editorials and websites, and by consulting experts. • The evidence base for genetic risk assessment and BRCA mutation testing for breast and ovarian cancer susceptibility as a screening strategy is limited by lack of studies demonstrating effectiveness, biases inherent in studies conducted in highly selected populations, and incomplete information on adverse effects.
Levy, et al. (2009) Guidelines for genetic risk assessment of hereditary breast and ovarian cancer: early disagreements and low utilization	**Key points:** • To identify women at high risk of hereditary breast and ovarian cancer and estimate their awareness of and experience with genetic testing for cancer risk. • Using guideline criteria, 0.96% of women were identified as being at high risk of hereditary breast and ovarian cancer. • Among high-risk women, 54.04% were aware of genetic testing for cancer risk, 10.39% had discussed genetic testing with a health professional and 1.41% had undergone testing for breast/ovarian cancer risk.

Citation	Content, Methods, Recommendations
	• Adjusting for survey year, high-risk women were more likely than average-risk women to have heard of genetic testing for cancer risk (RR, 1.3, 95% CI 1.2 – 1.4), to have discussed genetic testing with a health professional (RR 5.2, 95% CI 3.6 – 7.4), and to have undergone genetic testing for breast/ovarian cancer risk (RR 6.8, 95% CI 2.6 – 18.0). • Low provision of guideline-recommended advice to women for whom testing may be appropriate and of significant clinical benefit.
Fox, et al. (2015) The sooner the better: Genetic testing following ovarian cancer diagnosis	**Key points:** • To determine when women with a diagnosis of high-grade serous ovarian cancer would prefer to undergo genetic testing and factors that influence this preference. • 120 of the 355 women identified (33.8%) completed the questionnaires. The median age at time of ovarian cancer diagnosis was 57 years (range 35 – 84). The majority of participants in this study were offered (94.6%) and pursued (84.8%) genetic testing. In this cohort, testing was most frequently offered at diagnosis (41.8%) or during treatment (19.1%). In this study, women with high-grade serous ovarian cancer felt that genetic testing should be offered before or at the time of diagnosis (67.8%). Having a family history of breast or ovarian cancer was significantly ($p = 0.012$) associated with preferring genetic testing at an earlier time point in the disease course. • Our results demonstrate that women with high-grade serous ovarian cancer acknowledge the personal and clinical utility of genetic testing and support test implementation at the time of cancer diagnosis.
Burst (2017) Adjuvant chemotherapy for HER2-negative breast cancer.	**Key points:** • RS, EndoPredict, the Breast Cancer Index (BCI), and the PAM50 intrinsic subtype assay were suggested as means to identify patients with such a low chance of recurrence that the absolute benefit of chemotherapy may not justify the risk of toxicities. • By contrast, patients with higher scores on these assays have a sufficiently high risk of recurrence despite endocrine therapy that the addition of chemotherapy outweighs the risk of toxicities. • Given that the response to treatment is not uniform among all cancers, these assays may identify those cancers that, based on their biologic profile, are likely to have an excellent outcome with endocrine therapy alone versus those in which the addition of chemotherapy would substantially reduce the risk of recurrence.

References

Professional society guidelines/other:

American College of Medical Genetics, ACMG Policy: Mutation in Ashkenazi Jewish Women, Statement on Population Screening. ACMG Newsletter 7:9, 1996, Bethesda, MD. Website: https://www.acmg.net/StaticContent/StaticPages/Ashkenazi.pdf. Accessed April 5, 2017.

American College of Obstetricians and Gynecologists. Routine screening for hereditary breast and ovarian cancer recommended. March 23, 2009. Website: http://www.acog.org/About_ACOG/News_Room/News_Releases/2009/Routine_Screening_for_Hereditary_Breast_and_Ovarian_Cancer_Recommended. Accessed April 5, 2017.

American College of Obstetricians and Gynecologists (ACOG). ACOG Committee on Practice Bulletins—Gynecology, ACOG Committee on Genetics, Society of Gynecologic Oncologists. ACOG Practice Bulletin No. 103: Hereditary breast and ovarian cancer syndrome. *Obstet Gynecol*. 2009.;113(4):957 – 66.

Centers for Disease Control and Prevention (CDC). Breast Cancer Statistics. Available at: http://www.cdc.gov/cancer/breast/statistics/index.htm. Accessed April 5, 2017.

Hayes, Inc., Hayes Medical Technology Report. *Genetic Testing for Susceptibility to Breast Cancer*. Lansdale, PA: Hayes, Inc.: December 2002.

National Cancer Institute. BRCA1 and BrCA2 Cancer risk and genetic testing. Reviewed April 1, 2015. http://www.cancer.gov/cancertopics/causes-prevention/genetics/brca-fact-sheet. Accessed April 5, 2017.

National Cancer Care Network. NCCN clinical practice guidelines in oncology: Breast Cancer Screening and Diagnosis. Version 1.2014. Website: www.NCCN.org. Accessed April 5, 2017.

National Cancer Care Network. NCCN clinical practice guidelines in oncology. Genetic/familial high risk assessment: Breast and ovarian. Version 1.2015. Website: www.NCCN.org. Accessed April 5, 2017.

Nelson HD, Fu R, Goddard K, et al. Risk Assessment, Genetic Counseling, and Genetic Testing for BRCA-Related Cancer: Systematic Review to Update the US Preventive Services Task Force Recommendation. Rockville (MD). 2013. Website: http://www.uspreventiveservicestaskforce.org/uspstf12/brcatest/brcatestart.htm. Accessed April 5, 2017.

Nelson HD, Huffman LH, Fu R, et al. Agency for Healthcare Research and Quality (AHRQ): Genetic Risk Assessment and BRCA Mutation Testing for Breast and Ovarian Cancer Susceptibility: Evidence Synthesis No. 37. Sep. 2005. Available at: http://www.ahrq.gov/downloads/pub/prevent/pdfser/brcagensyn.pdf. Accessed April 5, 2017.

Moyer VA. Risk Assessment, Genetic Counseling, and Genetic Testing for BRCA-Related Cancer in Women: U.S. Preventive Services Task Force Recommendation Statement. *Ann Intern Med*. 2014;160(4). Available at http://www.uspreventiveservicestaskforce.org/uspstf12/brcatest/brcatestfinalrs.htm. Accessed April 5, 2017.

Peer-reviewed references:

Antoniou A, Pharoah PDP, Narod S, et al. Average risks of breast and ovarian cancer associated with BRCA1 or BRCA2 mutations detected in case series unselected for family history: a combined analysis of 22 studies. *Am J Hum Genet* 2003; 72(5): 1117–30.

Burst H. Adjuvant chemotherapy for HER2-negative breast cancer. In: Hayes D, ed. UpToDate. Waltham, Mass: UpToDate;2016. wwwuptodate.com. Accessed January 11, 2017.

Chen S, Iversen ES, Friebel T, et al. Characterization of BRCA1 and BRCA2 mutations in a large United States sample. *J Clin Oncol*. 2006;24(6):863 – 71.

Domchek SM, Friebel TM, Singer CF, et al. Association of risk-reducing surgery in BRCA1 or BRCA2 mutation carriers with cancer risk and mortality. *JAMA*. 2010;304(9):967 – 75.

Domchek SM, Rebbeck TR. Prophylactic oophorectomy in women at increased cancer risk. *Curr Opin Obstet Gynecol.* 2007;19(1):27 – 30.

Fox E, McCuaig J, Demsky R, Shuman C, The sooner the better: Genetic testing following ovarian cancer diagnosis. *Gynecol Oncol*. 2015;137(3):423-9.

Lee JM, Kopans DB, McMahon PM, et al. Breast cancer screening in BRCA1 mutation carriers: effectiveness of MR imaging—Markov Monte Carol decision analysis. *Radiology* 2008.;246(3):763 – 71.

Levy DE, Garber JE, Shields AE. Guidelines for genetic risk assessment of hereditary breast and ovarian cancer: early disagreements and low utilization. *J Gen Intern Med*. 2009;24(7):822-8. doi: 10.1007/s11606-009-1009-6. Epub 2009 May 20. PMID: 19455369.

Nanda R, Schumm LP, Cummings S, et al. Genetic testing in an ethnically diverse cohort of high-risk women: a comparative analysis of BRCA1 and BRCA2 mutations in American families of European and African ancestry. *JAMA* 2005; 294(15):1926 – 33.

Olopade O, Fackenthal JD, Dunston G, et al. Breast cancer genetics in African Americans. *Cancer.* 2003. 1; 97(1 Suppl): 236 – 45.

Palma MD, Domchek SM, Stopfer J, et al. The relative contribution of point mutations and genomic rearrangements in BRCA1 and BRCA2 in high-risk breast cancer families. *Cancer Res*. 2008. 1;68(17):7006 – 14.

Petrucelli N, Daly MB, Feldman GL. BRCA1 and BRCA2 Hereditary Breast and Ovarian Cancer. 1998 Sep. 4 (Updated 2011 Jan 20). In: Pagon RA, Bird TD, Dolan CR, et al., editors. GeneReviews™ (internet). Seattle, WA: University of Washington, Seattle; 1993 – 2015. website: http://www.ncbi.nlm.nih.gov/books/NBK1247/. Accessed April 15, 2017.

Rebbeck TR, Friebel T, Lynch HT, et al. Bilateral Prophylactic Mastectomy Reduces Breast Cancer Risk in BRCA1 and BRCA2 Mutation Carriers: The PROSE Study Group. *J Clin Oncol.* 2004;22(6):1055 – 1062.

Unger MA, Nathanson KL, Calzone K, et al. Screening for genomic rearrangements in families with breast and ovarian cancer identifies BRCA1 mutations previously missed by conformation sensitive gel electrophoresis or sequencing. *Am J Hum Genet*. 2000;67:841 – 50.

Walsh T, Casadei S, Coats KH, et al. Spectrum of mutations in BRCA1, BRCA2, CHEK2, and TP53 in families at high risk of breast cancer. *JAMA*. 2006;295(12):1379 – 88.

CMS National Coverage Determinations (NCDs):

No NCDs identified as of the writing of this policy.

Local Coverage Determinations (LCDs):

There are multiple LCDs for Genetic Testing. CMS Medicare Coverage Database website: https://www.cms.gov/medicare-coverage-database/search/search-results.aspx?CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=All&KeyWord=genetic+testing&KeyWordLookUp=Title&KeyWordSearchType=And&list_type=ncd&bc=gAAAAAAAAAAAAA%3d%3d&=& Accessed April 5, 2017.

Commonly submitted codes

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

CPT Code	Description	Comments
81162	BRCA1, BRCA2 (breast cancer 1 and 2) (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis and full duplication/deletion analysis	
81211	BRCA1, BRCA2 (breast cancer 1 and 2) (e.g., hereditary breast and ovarian cancer) gene analysis; full sequence analysis and common duplication/deletion variants in BRCA1 (i.e., exon 13 del 3.835kb, exon 13 dup 6kb, exon 14-20 del 26kb, exon 22 del 510bp, exon 8-9 del 7.1kb)	
81212	BRCA1, BRCA2 (breast cancer 1 and 2) (e.g., hereditary breast and ovarian cancer) gene analysis; 185delAG, 5385insC, 6174delT variants	
81213	BRCA1, BRCA2 (breast cancer 1 and 2) (e.g., hereditary breast and ovarian cancer) gene analysis; uncommon duplication/deletion variants	
81214	BRCA1 (breast cancer 1) (e.g., hereditary breast and ovarian cancer) gene analysis; full sequence analysis and common duplication/deletion variants (i.e., exon 13 del 3.835kb, exon 13 dup 6kb, exon 14-20 del 26kb, exon 22 del 510bp, exon 8-9 del 7.1kb)	
81215	BRCA1 (breast cancer 1) (e.g., hereditary breast and ovarian cancer) gene analysis; known familial variant	
81216	BRCA2 (breast cancer 2) (e.g., hereditary breast and ovarian cancer) gene analysis; full sequence analysis	
81217	BRCA2 (breast cancer 2) (e.g., hereditary breast and ovarian cancer) gene analysis; known familial variant	

ICD 10 Code	Description	Comments
C50.011-C50.919	Malignant neoplasm, female breast	
C50.021-C50.929	Malignant neoplasm, male breast	
C56.1	Malignant neoplasm of right ovary	
C56.2	Malignant neoplasm of left ovary	
C56.9	Malignant neoplasm of unspecified ovary	
C79.60	Secondary malignant neoplasm of unspecified ovary	
C79.61	Secondary malignant neoplasm of right ovary	
C79.62	Secondary malignant neoplasm of left ovary	
D05.00	Lobular carcinoma in situ of unspecified breast	
D05.01	Lobular carcinoma in situ of right breast	
D05.02	Lobular carcinoma in situ of left breast	
D05.10	Intraductal carcinoma in situ of unspecified breast	
D05.11	Intraductal carcinoma in situ of right breast	
D05.12	Intraductal carcinoma in situ of left breast	
D05.80	Other specified type of carcinoma in situ of unspecified breast	
D05.81	Other specified type of carcinoma in situ of right breast	
D05.82	Other specified type of carcinoma in situ of left breast	
D05.90	Unspecified type of carcinoma in situ of unspecified breast	
D05.91	Unspecified type of carcinoma in situ of right breast	
D05.92	Unspecified type of carcinoma in situ of left breast	
C79.81	Secondary malignant neoplasm of breast	
D07.39	Carcinoma in situ of other female genital organs (includes ovary)	
Z85.3	Personal history of malignant neoplasm of breast	
Z85.43	Personal history of malignant neoplasm of ovary	
Z80.3	Family history of malignant neoplasm of breast	
Z80.41	Family history of malignant neoplasm of ovary	

HCPCS Level II Code	Description	Comments
N/A		